Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
1st WHO International Standard for VZV NAT Assays
NIBSC code: 19/164
Instructions for use
(Version 2.0, Dated 14/03/2022)

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1. INTENDED USE

The 1st WHO International Standard for Varicella Zoster Virus (VZV) NAT assays, NIBSC code 19/164, is intended for the standardisation of nucleic amplification technique-based assays for VZV. It should be used primarily for the calibration of secondary reference standards. The material has been evaluated in a worldwide collaborative study involving 12 laboratories using a range of VZV NAT-based assays.

2. CAUTION

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. This preparation is not for administration to humans or animals

3. UNITAGE

Based on the ECBS consideration of the report of the study WHO/BS/2021.2405 [1] 19/164 was established as the First WHO International Standard for varicella zoster virus DNA for NAT-based assays with an assigned unitage of 7.0 log10 IU/vial.

4. CONTENTS

Country of origin of biological material: United Kingdom.
The preparation comprises of lyophilized whole Varicella Zoster virus (Clade 3), formulated in a universal buffer (10mM Tris-HCl pH 7.4, 0.5% Human serum albumin (HSA), 2.0% D-(+)-Trehalose dehydrate). Each vial contains the lyophilized equivalent of 1 mL of VZV in 10mM Tris-HCl pH 7.4, 0.5% Human serum albumin (HSA), 2.0% D-(+)-Trehalose dehydrate.

5. STORAGE

Vials of lyophilized material should be stored at -20ºC. Once reconstituted, contents are for single use only. This material has not been assessed for in-use stability of reconstituted material. Reconstituted material should not be stored without in-house validation studies performed by the end user.
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.
Vials have a screw cap; an internal rubber stopper is also present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The total contents of the ampoule should be reconstituted at room temperature with 1 mL of nuclease-free molecular-grade water and left for 20 minutes with occasional gentle agitation before use. Recommended for single use only.
Once reconstituted, the International Standard should be further diluted into a matrix comparable to the clinical samples being tested. The material is designed to be used in conjunction with the extraction step of the NAT procedure. The International Standard should be used to generate a standard curve for the calibration of secondary reference materials which can then be assigned a concentration in International Units [2].

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials. It is the policy of WHO not to assign an expiry date to their International reference materials. Accelerated degradation studies have indicated that this lyophilized material is suitably stable, when stored at -20ºC, for the assigned value to remain valid until the material is withdrawn or replaced [1].

Users who have data supporting any deterioration in the characteristics of this reference preparation are encouraged to contact NIBSC.

9. REFERENCES

[1] https://www.who.int/publications/m/item/WHO-BS-2021.2405
[2]https://www.who.int/bloodproducts/norms/SecStandManWHO_TRS_1004_web_Annex_6.pdf

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of the collaborative study participants [1].

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: White solid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
Flammable:	No	Handling: See caution, Section 2	
Other (specify):	Contains infectious VZV		
Toxicological properties			
Effects of inhalation:	Not established, avoid inhalation		
Effects of ingestion:	Not established, avoid ingestion		
Effects of skin absorption:	Not established, avoid contact with skin		
Suggested First Aid			
Inhalation:	Seek medical advice		
Ingestion:	Seek medical advice		
Contact with eyes:	Wash with copious amounts of water. Seek medical advice		
Contact with skin:	Wash thoroughly with water.		
Action on Spillage and Method of Disposal			
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.			

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 1.0g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.